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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,623	03/22/2002		Eberhard Fritz	3993.003	4998
7:	590	11/08/2002			
Stephan A Per	ndorf		EXAMINER		
Pendorf & Cutl PO Box 20445			GILBERT, SAMUEL G		
Tampa, FL 33	622-0445		ART UNIT	PAPER NUMBER	
,			3736		
			DATE MAILED: 11/08/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.		Applicant(s)	/					
		10/018,623		FRITZ ET AL.	an					
	Office Action Summary	Examiner		Art Unit	<u> </u>					
	•	Samuel G Gilbert		3736						
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address									
Period for Reply										
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).										
Status										
1)	Responsive to communication(s) filed on		al							
2a) ☐	,,,,=	his action is non-fin		accoution as to th	a marite is					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.										
Disposition of Claims										
4) 🖾	4) Claim(s) 23-48 is/are pending in the application.									
4a) Of the above claim(s) is/are withdrawn from consideration.										
5)	Claim(s) is/are allowed.									
6)🛛	6)⊠ Claim(s) <u>23-48</u> is/are rejected.									
, —	Claim(s) is/are objected to.									
	Claim(s) are subject to restriction and/	or election requiren	nent.							
• •	on Papers									
9) The specification is objected to by the Examiner.										
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.										
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).										
11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.										
12) The oath or declaration is objected to by the Examiner.										
Priority under 35 U.S.C. §§ 119 and 120										
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).										
a) ☐ All b) ☐ Some * c) ☐ None of:										
1. Certified copies of the priority documents have been received.										
	2. Certified copies of the priority documents have been received in Application No									
	3. Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.										
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).										
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>										
Attachment(s)										
2) Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	4)		y (PTO-413) Paper No Patent Application (PT						

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#### **DETAILED ACTION**

### Information Disclosure Statement

The information disclosure statement filed 5/30/02 has been considered.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 – "seeds (treating elements)" is indefinite.

Claim 28 – in lines 1-2 "the one or more deflection site(s)" lacks antecedent basis.

Claim 30 – in lines 1-2 "the one or more deflection site(s)" and in lines 2-3 "the tube" lack antecedent basis.

Claim 38 – in lines 4-5, "optionally a guide wire and a second lumen therefore" is indefinite because it is unclear if the applicant is claiming the recited elements or not. In line 6, "seeds (treating elements) is indefinite. Further, "a second lumen" lines 4-5 has been set forth without a first lumen.

Claim 41 – "magnetic means" lines 1-2 has been set forth without a positively recited function.

Claim 43 - "seeds (treatment elements)" line 10 is indefinite.

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Claim 47 – "magnetic means" lines 5-6 is set forth without a positively recited function.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-27, 31, 35-37, 43-46, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Liprie (5,833,593).

Claims 23, 24 – element –660- show seeds, element –680- is a containment means and –60- provides an elongate container(hollow cylinder) having a deflection site, applicant's attention is invited to figures 3A-3D generally at –295-(element –295-itself is not the deflection site but shows the location of the deflection site.

Claim 25-27 – the container can be Nitinol. Applicant's attention is invited to column 7 lines 33-49.

Claim 31 – as shown in figure 6, radioactive elements –660- have rounded ends.

Claim 35 - -680- can be titanium, applicant's attention is invited to column 11 lines 39-47.

Claims 36 and 37 - see column 8 lines 48-50.

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Claim 43-46 and 48 – Liprie 5,556,389, is incorporated by reference into Liprie 5,833,593. Liprie teaches delivering a catheter to a treatment site and then delivering the radiation source to the treatment site allowing the radiation source to remain at the treatment site for a desired time period, removing the radiation source and removing the catheter. See above for particulars of the radiation source.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 32, 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie 5,833,593. Liprie et al teaches the device as claimed but does not teach the use of spacers. Spacers are well known in the radiation therapy arts and are used for several reasons including forming the desired radiation pattern or for imaging the implanted devices. Cutrer 5,997,463 teaches spacers –1014-(spheres) for use as markers. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use spacers as taught by Cutrer with the device of Liprie to provide marker means as taught by Cutrer.

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Claims 38-40 and 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (5,833,593). Liprie 5,556,389, is incorporated by reference into Liprie 5,833,593. Liprie teaches a catheter and radiation source as claimed but uses a single lumen for the guide wire and radiation treatment. The examiner is taking official notice that it is old and well known in the art that radiation treatment catheter can include separate guidewire and treatment lumens. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use separate treatment and guidewire lumens in the device of Liprie as is well known in the medical arts as a substitution of functionally equivalent elements. See above for particulars of the treatment elements.

Regarding claim 42 – Liprie 5556389 column 6 sets forth the use of fluoroscopy to position the device.

# Allowable Subject Matter

Claims 28-30, 34, 41, and 47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 6,273,851; 5,857,956; 5,863,284; 5,683,345; 5,503,614; and 5,460,592 teach related therapy devices.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G Gilbert whose telephone number is 703-308-3553. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max. Hindenburg can be reached on 703-308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Samuel G Gilbert Primary Examiner Art Unit 3736

sgg November 4, 2002